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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,945	02/11/2000	Matthew J. Scanlan	L0461/7081-(JRV)	5906

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EXAMINER
DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/502,945	SCANLAN ET AL.	
	Examiner	Art Unit	
	Natalie A. Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,37-40 and 55-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,37-40 and 55-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendment filed 22 January 2002 (Paper No: 11) is acknowledged. Accordingly, claim 6 is amended and claims 6, 37, and 57-67 are pending.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112 1st Withdrawn

1. Rejection of claims 6, 37-40, 58, 63, and 67 (paragraphs 4-6) under 35 U.S.C.112, first paragraph is withdrawn in view of arguments.

Claim Rejections - 35 USC § 112 2nd Withdrawn

2. Rejection of claims 6 and 38-40 under 35 U.S.C.112, second paragraph is withdrawn in view of amendments.

Claim Rejections - 35 USC § 101 Withdrawn

3. Rejection of claims 6, 37-40, 58, 63, and 67under 35 U.S.C. 101 is withdrawn in view of arguments.

New Rejections

Abstract

4. The abstract of the disclosure is objected to because it is not in compliance with Rule 37 CFR 1.72(b). The content of a patent abstract should be such as to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to ascertain quickly the

character of the subject matter covered by the technical disclosure and should include that which is new in the art to which the invention pertains. The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 250 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. Claims 6, 37, and 57-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The nucleic acid molecule in claim 6(a) is indefinite. It is not clear to which sequence the complementary sequence is complementary to: the nucleic acid which encodes the cancer associated antigen, the second nucleic acid molecule (SEQ ID NO: 8-18), or both. Furthermore, it is uncertain if the nucleic acid consists of SEQ ID NO: 8-18 or a sequence complementary thereto and whether SEQ ID NO: 8-18 encodes a cancer associated antigen.

7. Claim 37 recites " stimulating an immune response to at least one protein." This is indefinite as it is not clear how to stimulate an immune response in at least one protein.

8. Claims 6 and 57-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention is drawn to a nucleic acid molecule, which encodes a cancer associated antigen. The specification discloses expression of clones NY-Co-8, 9, 13, 16, 20 and 38 in colon, renal, lung, and breast cancer (p. 8), but not in any other cancer. The specification does not disclose which clone comprises SEQ ID NO: 1, 2, 3, 4, or 5. Since there is no teaching in the disclosure or the prior art teaching indicating which SEQ ID NO: correlates to the clones NY-Co-8, 9, 13, 16, 20 and 38, one would not know how to use the invention. In view of the lack of said teachings and insufficient guidance as to how to which clone conditions which SEQ

ID NO, one of skill in the art would not be able to practice the claimed invention because undue experimentation would be required.

9. Claims 37-40 and 62-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 37 is drawn to a composition of matter useful in stimulating an immune response. The disclosure indicates that the invention may be used to treat conditions characterized by expression of one or more proteins, by administering one or more proteins to a subject (p. 14). The disclosure lacks enablement because there is no guidance or exemplification of which condition(s), characterized by expression of one or more proteins may be treated by stimulation of an immune response. Since there is no teaching in the disclosure or the prior art teaching the condition(s), which may be treated by stimulating an immune response, by administration of the composition, one would not know how to use the invention. In view of the lack of said teachings, working examples, and insufficient guidance as to how to which condition(s) may be treated using the claimed composition, one of skill in the art would not be able to practice the claimed invention because undue experimentation would be required.

10. Claims 6 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 6 is drawn to an isolated protein, which is encoded by a nucleic acid comprising SEQ ID NO: 1-5, but there is no evidence in the specification that indicates the translation of said nucleic acid into protein. Examples 2-7 in the disclosure show expression of SEQ ID NO: 1, 2, 4, and 5 in the serum of patients with renal, colon, lung and breast cancer using probes (p. 7), RACE (p.9), and Northern blots (p. 11). These assays do not detect the presence of proteins, they only detect the expression of nucleic acids (RNA), as probes were used to confirm the expression of SEQ ID NO: 1-2 (p. 7, line 15). Accordingly, it would be unpredictable to use the invention as claimed because the specification does not indicate the expression of protein. An article by Alberts, et al. is cited in order to establish the general state of the art and the level of predictability of protein translation. Those of skill in the art, recognize

that expression of mRNA does not dictate the translation of such mRNA into a polypeptide. Alberts, et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. Thus, predictability of protein translation is not necessarily contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. Therefore, one of skill in the art would not know how to use the invention as claimed because it is unpredictable whether the nucleic acids of SEQ ID NO: 8-18 were in fact translated protein.

11. Claims 6, 37-40, and 57-67 are rejected less than 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all it limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.

The invention is drawn to a protein, which is encoded by a nucleic acid(s) comprising SEQ ID NO: 1-5 or degenerates or complements thereof and composition comprising a protein(s). There are no examples disclosed that conveys to one of skill in the art that the applicant was in possession of claimed proteins, nucleic acid degenerates or complements

thereof to SEQ ID NO: 1-5 and composition comprising proteins. There is no actual reduction to practice, sufficient descriptive information, such as definitive structural features, which are critical to polypeptide activity, or complete detailed description of the function of claimed invention indicating that the claimed proteins, nucleic acid degenerates or complements thereof to SEQ ID NO: 1-5 and composition were indeed isolated, produced, and assayed for the uses disclosed. As indicated above, there is no teaching or exemplification in the specification disclosing the translation or synthesis of a protein, the use of degenerates or nucleic acid complements, which encode a protein or a composition that stimulates an immune response. Accordingly, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
March 19, 2002

ANTHONY C. CAPUTA
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